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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,572	02/11/2004	David Burton	24,577-45CIP	6003

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John F. Klos, Esq.
Fulbright & Jaworski L.L.P.
80 South Eighth Street, Suite 2100
Minneapolis, MN 55402-2112

EXAMINER	
DIXON, ANNETTE FREDRICKA	
ART UNIT	PAPER NUMBER
3771	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/777,572	BURTON, DAVID	
	Examiner	Art Unit	
	Annette F. Dixon	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *RCE 9/18/08*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,14-26 and 28-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11,14-26 and 28-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is in response to the request for continued examination filed on September 23, 2008. Examiner acknowledges claims 1-11, 14-26, 28, 29, and 30 are pending in this application, with claims 1, 8, 14, 15, 17, 23-26, and 28-30 having been currently amended, and claims 12, 13, 27, 31 and 32 having been cancelled.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 23, 2008 has been entered.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-11, 14-20, 23-26, 28, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sullivan (5,243,971) in view of Brown (6,032,065) and Miles (5,353,788).

As to Claim 1, Sullivan discloses a mask assembly (11, Figure 8a) comprising: a body (the combination of elements 24, 34, and 13) having an inner surface (34), and external surface (24) and a perimeter surface (13); and a forehead support (31) connected to the body (the combination of elements 24, 34, and 13), a control system (14), and a gas delivery device (10) in communication with said breathing mask (11), said gas delivery device (10) delivering gas to the patient (12) based on a control system (14) determination (Column 3, Line 55 thru Column 4, Line 8). Yet Sullivan does not expressly disclose an EEG sensor located on the forehead support, nor the control system adapted to receive a signal from the EEG sensor for determining the sleep stage of the patient. However, at the time the invention was made the use of EEG sensors on the forehead and the control system cooperatively working with the EEG sensor to determine the patient's sleep stage was known. Regarding the placement of an EEG sensor to the forehead support, Brown teaches the use of a pair of EEG sensors (28) on the patient's forehead for sensing the electrical wave forms of the patient's brain activity for the treatment of sleep disorders. (Column 3, Lines 35-38). Regarding the cooperative relationship between the sensors and the gas delivery device, Miles teaches the use of sensors such as EEG for gathering information and modifying the air flow pressure cycle for the purpose of providing appropriate medical treatment as a result of the physiological data of the patient. (Column 4, Lines 55-66). Therefore, it would have been obvious to one having ordinary skill in the art to modify the forehead support of Sullivan to include an EEG sensor as taught by Brown to enable the monitoring of sleep disorders and to modify the processor of Sullivan to include the

cooperative relationship between the sensors and gas delivery as taught by Miles to enable accurate respiratory therapy based upon the physiological needs of the patient.

As to Claim 2, Sullivan discloses the perimeter surface (13) includes a padding material having a thermosensitive coating. Specifically, Sullivan discloses the membrane is molded from a soft, flexible plastic material. Intrinsically, as the perimeter surface (13) is made from a softer and different material than the rest of the mask (11) the perimeter surface (13) is more sensitive to temperature.

As to Claim 3, Sullivan discloses a bar (30) extending in a lateral direction from the forehead support (31).

As to Claims 4 and 11, Miles discloses additional sensors such as blood oxygen saturation may be utilized to calculate the physiological data of the patient. Regarding the location of the sensor on the forehead, it would have been obvious to one having ordinary skill in the art at the time the invention was made to change the location of the blood oxygen sensor to the forehead support, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

As to Claim 5, Brown discloses the electrodes are made from a pad comprising a conductive carbonized rubber material. (Column 3, Lines 9-29).

As to Claims 6, Sullivan discloses a strap (the combination of elements 42 and 43) extending from the mask (11), and wherein a physiological sensor is located on the strap. Regarding the location of the sensor on the strap, it would have been obvious to one having ordinary skill in the art at the time the invention was made to change the

location of the sensor to the strap, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

As to Claim 7, Brown discloses the use of sensors (30) to measure EOG. (Column 3, Lines 38-47).

As to Claims 8, 14, 17, 18, and 20, please see the rejection of claim 1. Regarding the plurality of sensors, Brown discloses a plurality of sensors utilized to calculate EEG (28), EOG (30) and EMG (32).

As to Claim 9, Brown discloses an EMG sensor (32).

As to Claim 10, Miles teaches the use of physiological sensors such as ECG (Column 7, Line 40).

As to Claims 15 and 19, Miles discloses the use of pulse oximetry sensor and an ECG sensor (Column 7, Line 40 and 43) yet does not expressly disclose the location of the sensors. Regarding the location of the sensor on the mask, Miles teaches sensors may be mounted on the mask. (Column 4, Lines 44-45).

As to Claim 16, Brown discloses an EMG sensor (32) and Sullivan discloses the use of a strap (the combination of elements 42 and 43); yet the placement of the sensors on the strap has not been discussed. Regarding the location of the sensor on the strap, it would have been obvious to one having ordinary skill in the art at the time the invention was made to change the location of the sensor to the strap, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

As to Claims 23 and 26, Miles discloses a first thermal sensor (Column 4, Lines 55-60) on the interior surface (Column 4, Lines 33-37) and a second thermal sensor (Column 4, Lines 33-37). Miles discloses detecting a temperature change (via processor, 12) in the first or second thermal sensor (Column 5, Lines 20-68 and Column 6, Lines 1-30). Yet Miles does not expressly disclose the location of the second sensor to be located adjacent to the mouth of the patient. Regarding the location of the sensor near the mouth, it would have been obvious to one having ordinary skill in the art at the time the invention was made to change the location of the sensor near the mouth, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

As to Claims 24, 25, and 29, Miles disclose the detection of body movement via a sensor (Column 7, Lines 45-48). Regarding the location of the sensor on the mask, Miles teaches sensors may be mounted on the mask. (Column 4, Lines 44-45).

As to Claim 28, Sullivan discloses a support pad (31) in contact with the forehead of the patient.

5. Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sullivan (5,243,971), Brown (6,032,065) and Miles (5,353,788) as applied to claim 18 above, and further in view of Cui et al. (5,584,296).

As to Claims 21 and 22, the combination of the prior art references teaches a mask assembly with a plurality of sensors, yet does not expressly disclose the use of light sources and high pass filters. However, at the time the invention was made the

use of light sources and high pass filters was known. Specifically, Cui teaches attaching a light source (36) and a light sensor (32) on a mask so that the light source and light sensor are positioned to contact a person's forehead (Fig 1), illuminating the light source (Column 2, Lines 63-66); detecting the light from the light source (via 32 and 34) as it deflects from the person's skull; and converting (via 20) the detected light into an analog signal. Regarding the filtering technique, the technique utilized would be within the conventional methods of filtering sound since it has been held to be within the general skill of a worker in the art to select a known filtering technique on the basis of its suitability for the intended use as a matter of obvious design choice. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the sensors of Miles to include a light source and sensors as taught by Cui for the purpose of reading and detecting sensor information.

6. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sullivan (5,243,971), Brown (6,032,065) and Miles (5,353,788) as applied to claim 14 above, and further in view of Tripp, Jr. (H1039).

As to Claim 30, the combination of the prior art references teaches a mask assembly with a plurality of sensors, yet does not expressly disclose a mask seal leakage detector. However, Tripp teaches a perimeter of the mask is adapted to sense leaks (Column 11, Lines 46-53). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the sensors of Miles

to include a leakage detector as taught by Tripp to detect the passage of air been the mask assembly and the external environment.

Response to Arguments

7. Applicant's arguments with respect to claims 1-11, 14-26, and 28-30 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Sullivan et al. (5,199,424; 6,398,739; and 6,635,021) and Kwok et al. (6,119,693) disclose additional respiratory masks for the treatment of sleep apnea.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette F. Dixon whose telephone number is (571) 272-3392. The examiner can normally be reached on Monday thru Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Annette F Dixon
Examiner
Art Unit 3771

/Annette F Dixon/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771